

Revisions made in Response to Comments or  
Suggestions from DHHS/ASPE, including FDA,  
In Consultation with OMB/OIRA, while the  
Document was Under Review at OMB/OIRA

April 30, 2003

enforcement actions, including other actions that we subsequently follow with seizure actions, then our estimate of the number of administrative detentions per year could be significantly larger. Examples of other types of enforcement actions include detentions without physical examination (DWPE) and requests to states to embargo food.

We assume that the number of administrative detentions might include 0 to 100 percent of the number of Class I recalls and instances in which we moved directly to seize food, and 0 to 10 percent of the number of times we referred matters to state authorities. In all cases, we based the low end of the range on the fact that we do not know if we would have used administrative detention, even if we had the authority to do so, and the criteria for using administrative detention had been met. Analyzing all the factors that would lead us to choose one enforcement action over another is beyond the scope of this analysis. We chose 100 percent as the high end of the range for Class I recalls because the criteria for Class I recalls is quite similar to the criteria for administrative detention. We chose 100 percent as the high end of the range for instances in which we move directly to seize food as a practical expedient because the small number of actions implies that such information would have had little or no

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impact on our cost estimates. We chose 10 percent as the high end of the range for state referrals because our

experience with those actions suggests that only about ten percent of recent referrals involved concerns or situations that would have met the criteria for administrative detention. The other referrals do not appear to meet the criteria for administrative detention.

In fiscal year 2002, we initiated 184 Class I recalls involving food that posed a risk of serious adverse health consequences or death to humans or animals. In the same year, we initiated 16 seizures that may have involved food products that posed hazards to human or animal health. In the last twelve months, we estimate that we referred 234 of such matters to state authorities.

These numbers are repeated in Table 1. Based on this information, we estimate that we might administratively detain

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These numbers are repeated in table 1 of this document. Based on this information, we estimate that we might administratively detain food 0 to 223 times per year.

TABLE 1.—SUBSTITUTIONS PER YEAR

Action	Estimated Number of Substitutions of Administrative Detention for Other Enforcement Actions per Year
Class I recalls	0 to 184
No preliminary action (move directly to seizure)	0 to 16
No preliminary action (refers matter to State authorities)	0 to 23
Total	0 to 223

*Estimate of the proportion of cases in which the food subject to administrative detention turns out to be not violative*

Some of the costs that we will discuss later are only relevant if we eventually determine that food that we have administratively detained is not violative. We do not know the proportion of cases in which we might administratively detain food that we later determine to be not violative. This rate depends on the type of information we receive, and the level of risk aversion we adopt when we apply the criteria allowing us to use administrative